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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/407,182 | 09/29/1999 | DONALD L. SIEGEL | 9596-43U1-(J) | 2410 |

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05/08/2002

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EXAMINER

BUDENS, ROBERT D

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/13/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-23 is/are pending in the application.
Of the above, claim(s) 20-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2/12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

Applicant's election without traverse of Group I, claims 10-19 in Paper No. 8 is acknowledged.

The Examiner acknowledges Applicant's Response to Restriction Requirement, Paper No. 8, filed February 13, 2002. In view of Applicant's Response, the status of the claims is as follows: Claims 1-9 and 24-29 have been canceled; Claims 20-23 are withdrawn from consideration as being directed to a non-elected invention; Claims 10-19 are currently pending before the Examiner.

Claim 11 is objected to under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 uses a sedimentation step "effected by centrifugation." However, independent claim 10 indicates that sedimentation is carried out "under the force of gravity." The force of gravity and centrifugal force are different forces of nature and, hence, dependent claim 11 fails to further limit independent claim 10.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards

as the invention. Claim 10 is vague and indefinite in the recitation "inert particles and a second antibody" since it is unclear whether the second antibody is attached to the inert particles or is simply an additional reagent in the microtube. Amendment of claim 10 to more clearly point out and define what is intended by the language "inert particles and a second antibody" would obviate this rejection. Claim 10 is further vague and indefinite in the recitation "located upon or within a top layer" and "located within a lower layer" since it is unclear what amount of distance would distinguish a top layer from a lower layer. It is unclear that the same inert particles would produce precise and discreet layers that would be readily recognizable as a "top layer" and a "lower layer." Amendment of claim 10 to more particularly point out and define what would constitute a "top layer" and a "lower layer" would obviate this rejection. Claims 18-19 are vague and indefinite in the recitation "antigen-bearing moiety" since the language lacks antecedent basis in claim 10. Amendment of claims 18-19 to provide for proper antecedent basis would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed methods utilize "inert

particles and a second antibody." However, there is no indication whether the second antibody is attached to the inert particles in a manner of an indirect agglutination immunoassay or whether the antibodies are separate reagents intended to agglutinate the bacteriophage-cell complexes themselves while the inert particles serve a different function in the assay. Many well-known agglutination assays such as latex agglutination assays or magnetic particle assays utilize inert or magnetic particles carrying secondary antibodies on the surface of the inert or magnetic particle. These antibody-bearing inert particles then bind the target of interest and agglutinate. However, it is unclear from the claimed method steps that Applicant's claimed methods utilize inert particles and second antibodies in an analogous manner or in some other way. In the absence of sufficient guidance and teachings, one skilled in the art would not be able to use the methods of the claimed invention with a reasonable likelihood of success and without undue experimentation.

Applicant's claimed invention is deemed to be FREE OF THE ART. It is noted that parent application Serial No. 08/884,046 has issued as U.S. Patent No. 5, 985,543. The closest prior art to the instant application as well as to the patented methods of the parent application is Siegel et al., *Blood* 83(8):2334-2344, 15 April 1994, submitted by Applicant in Paper No. 2 1/2. Siegel et al. discloses expressing anti-Rh(D) antibodies on M13 filamentous phage (see page 2335, first full paragraph) using methods well known in the art for expressing antigen-binding fragments on filamentous phage for studying of red blood cell autoantibodies and alloantibodies (see Abstract). Siegel et al. also teach agglutinating Rh(D)+ red blood cells using Fab fragments using well known techniques of indirect agglutination. Siegel et al. uses a secondary antibody, goat anti-human F(ab')₂ antibodies, to agglutinate Fab-coated red blood cells since Fab fragments lack the capacity to agglutinate cells. However, as Applicant successfully

argued in the parent application, Siegel et al. did not disclose agglutination of cells but, rather, using flow cytometry which cannot be utilized with agglutinated cells. Therefore, Siegel et al. could not have disclosed methods of agglutination. Further, the prior art does not disclose or fairly suggest using an second antibody directed to a bacteriophage. Therefore, the methods of the claimed invention distinguish over the art.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
May 6, 2002